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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,314	03/17/2004	Van Le Huynh	ECV-5539CON	3894

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EDWARDS LIFESCIENCES LLC
One Edwards Way
Irvine, CA 92614

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/802,314

Applicant(s)

HUYNH ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Totten et al. (4477930). Totten et al. disclose a tubular fabric with a stent frame and a ring insert, see Figs. 1, 6, 7, and col. 4, lines 8-11. Claims in a pending application should be given their broadest reasonable interpretation, *In re Hyatt*, 54 USPQ 2d 1664 (Fed. Cir. 2000). Therefore, the Totten suture ring is configured to pivot or moveable between two positions since it is made of an elastomer, col. 4, lines 12,13, and Fig. 8 illustrates that the sewing ring can pivot about the edge. Totten discloses the sewing ring to be pliable or suture permeable (col. 4, line 16), thus it can be interpreted to be bi-stable because of its flexibility and placement at a seam or edge as seen in Fig. 8. The ring can be considered “**generally** frusto-conical” as seen in Figs. 7,10. Totten also discloses the fabric covers the ring and connects the ring to the stent periphery at a seam, col. 5, lines 12-17. Fig. 8 also shows the insert ring to be “substantially planar.”

Claims 1-7,11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanney et al. (5843179). Vanney et al. disclose heart valve with a generally annular stent frame (Fig. 15C) and a ring insert, see Figs. 6A, 7A,9A. Claims in a pending application should be given their broadest reasonable interpretation, *In re Hyatt*, 54

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USPQ 2d 1664 (Fed. Cir. 2000). Since the ring is covered (col. 11, lines 16,17) with fabric it is suture-permeable. Vanney discloses the ring is configured to pivot or moveable between two positions i.e. (movement toward the inflow, Figs. 6B,7B,9B) since it is made of an elastomer, col. 10, lines 27-33. It can be interpreted to be bi-stable because of its flexibility and placement at a seam or attachment line, col. 10, lines 61-66. Fig. 15D shows the ring being planar. Vanney additionally discloses that the fabric can cover both the ring and a portion of the heart valve, col. 10, lines 54,55.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Huynh et al. (5928281). Totten is explained supra. However, Totten does not disclose alternating thick and thin regions in the insert ring. Huynh teaches (Figs. 27, 32) that an insert ring for a suture ring is provided with thick and thin regions. It would have been obvious to one of ordinary skill in the art to use thick and thin regions as taught by Huynh in the sewing ring of Totten such that it provides more stability in maintaining the fabric covering to the ring.

Claims 10,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Reichart et al. (4626255). Totten is explained supra. However,

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Totten does not disclose the insert ring with a radially undulating shape. Reichart et al. teach (Fig. 1) that the sewing ring has an undulating shape. It would have been obvious to one of ordinary skill in the art to use the undulating shape for the sewing ring as taught by Reichart with the heart valve of Totten in order to more closely match the shape of the natural annulus to where the prosthetic valve is being implanted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738


BRIAN E. PELLEGRINO
PRIMARY EXAMINER